HSA
Health Sciences Authority

setting standards

HEALTH SCIENCES AUTHORITY

taking on a new identity

A strong upward direction and movement represents a dynamic, progressive, forward-looking organisation of excellence.

The blue arch symbolises our global outlook and global renown. The two white strokes suggest progression and continuous development. The integrated blue and white segments express our strong collaborative and interactive approach. The firm but fluid “tick” communicates confidence in HSA approval and regulatory authority.

Our choice of blue colour projects our foundation of professionalism, strength and integrity. The refreshing golden yellow signifies our vibrant, innovative and people-oriented culture.

Viewed in its totality, our logo encapsulates our vision, mission and orientation towards the future.

vision

To be world class
for scientific and regulatory
expertise in Health Sciences

mission

To excel in applying science to:

- support healthcare services and regulation
- serve the administration of justice
- enhance safety in our community

values

- We are committed to professional excellence
- We create value for our clients
- We uphold our professional integrity
- We value and nurture our staff
- We encourage innovation and enterprise

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Prof Hang Chang Chieh
Chairman

chairman's statement

As the world's medical and scientific communities are exploring new frontiers in genomic research, biotechnology, biomedical science and investigative science, Singapore must ensure that it stays ahead, ready and responsive in the application of science to safeguard public health and safety.

The formation of the Health Sciences Authority (HSA) on 1 April 01 marked a significant milestone in our formidable effort to meet this increasing pace of change in the face of globalisation and growing complexity in this field.

Foundation for the future

Whether in the emergence of novel healthcare products of combined technologies that require new expertise and systems to make good evaluations before they can be used by patients, or in investigative, scientific and analytical work for and beyond judiciary and statutory means, a broad range of disciplines, expertise and capabilities will have to be engaged.

The formation of HSA sees a larger and stronger critical core of medical, pharmaceutical and scientific expertise that can come together synergistically to achieve greater scientific and regulatory excellence. This unique integration and combination of expertise across different specialist fields is deployed through HSA's 8 professional centres, yet all under one roof.

Coming together as a single agency also means that Singaporeans and corporations enjoy a seamless regulatory process for all therapeutic products, including new and innovative products that promise to transform the way doctors diagnose, treat and prevent diseases that today still afflict many in our society.

Setting Standards

For HSA to achieve its mission of excelling in applying science to safeguard public health and safety demands, HSA has begun to engage new strategies, and meet new standards.

Our impetus to maintain a global perspective in this age of globalisation and global access to information ensures that the quality, safety and efficacy of healthcare and blood products available in Singapore and the quality of investigative and analytical service are benchmarked with the best in the world. Networks are being built and strengthened with our leading counterparts in the US, UK, Europe and Australia in order to keep pace with the latest technology and the best international practices and standards.

We also recognise that in the present climate of increasing globalisation, more and more biological and biotechnological products as well as traditional and complementary therapeutics will move freely across lowered market barriers. Regulatory decisions are expected to be not just effective and transparent, but also be made in a timely manner to ensure access to improve the quality of life. Strategic alliances with our overseas regulatory counterparts will therefore speed up information exchange and collaboration, so essential in meeting the challenges of protecting public health and safety whilst yet ensuring timely access. In FY 02, we look forward to formalising our collaboration with the Therapeutic Goods Administration, Australia.

To meet these new challenges, it would be necessary for the depth and breadth of our professional expertise and capability to be developed to the level of international recognition. New capabilities in molecular biology, genetics, toxicology and pre-clinical evaluation will enable us to leverage on our scientific expertise and resource to the optimum for the benefits of our stakeholders. Synergies between various specialised fields will need to be forged. Already we have begun to seek expert consultancy and training from the countries that enjoy world renown status for our different domains of work. We see an increase in different levels and areas of professional exchanges, as well as our professional representations in international programmes ranging from drug quality assurance, food safety, radiation protection, forensic inspection and audit, blood quality and safety, regulatory evaluation to regional and global harmonisation. We continue to encourage and acknowledge innovation and enterprise as well as research and development that will ultimately be useful for our agenda.

Closing Remarks

In this first infancy year of being, I am happy to note that aside from continued effort to implement the ongoing developmental projects, HSA has laid a strong foundation to position itself to take on the challenges ahead. For the numerous developments in the year under review, I would like to express my gratitude to the Board Members for their invaluable advice. To the management and staff of HSA, I convey my appreciation for their dedication, passion and commitment to their professional work and their contribution to the organisation. Working together as one family for one future, HSA will move closer to its vision to being world class for scientific and regulatory expertise in health sciences.

Professor Hang Chang Chieh
Chairman

Dr Clarence Tan
Chief Executive Officer

ceo's report

In a world where science, medicine and technology increasingly combine and converge to create ever more advanced and complex solutions, products and services in healthcare, the mission of safeguarding public health and well-being effectively and timely has become more critical than ever.

A key priority for the first year of HSA since formation on 1 April 01 has been consolidation to sharpen our professional excellence and organisational efficiency. *Our strategic reviews directed at two levels – enhancing the effectiveness of our professionals and enhancing the efficiency of our processes – will ensure that HSA remains relevant, responsive and ready to accomplish our mission today and to face tomorrow's challenges.*

Promoting Professional Excellence
High level strategic objectives for the Authority were defined at the Vision, Mission & Strategy workshop held before the formation of HSA. These high level strategic objectives were then cascaded to the 8 Professional Centres through a comprehensive process of environmental scanning, SWOT analysis, and scenario planning, culminating with the implementation of the Balanced Scorecard.

On the regulatory front, a comprehensive review of the regulatory framework for healthcare products has been initiated to consolidate the laws governing medicines and health-related products, including medical devices, under our purview. Our stakeholders can look forward to a progressive and pragmatic regulatory environment for healthcare products that is benchmarked with the leading regulatory agencies worldwide.

To effectively deliver our mission to safeguard public health and safety, we recognise that transparency of our policies and processes is necessary to build public confidence and increase public awareness of safe practices when using the products we regulate.

HSA is in touch with our stakeholders. A new initiative by our Centre for Pharmaceutical Administration will result in an abridged drug evaluation pathway that pharmaceutical companies can make use of to reduce their timeline for marketing approval of products which have been evaluated and approved by our benchmark regulatory agencies. To address the increasing worldwide trend of counterfeit drugs, our surveillance and enforcement functions will continue to be strengthened and globally networked.

The Voluntary Product Registration Scheme for medical devices, to be rolled out by our Centre for Medical Device Regulation, bears testimony to how positive engagement in a strategic partnership with industry can strike a balance between ensuring the safety and effectiveness of medical devices available in Singapore and address industry concerns to minimise delay in the time to market.

Our comprehensive post-marketing surveillance programme continues to ensure that the benefits of approved healthcare products continue to outweigh any newly-discovered adverse effects. This programme is being progressively extended beyond western drugs, cosmetics and Chinese proprietary medicines to cover health supplements, biologics, medical devices and blood products. Efforts are being made to further strengthen our network with overseas regulatory agencies for swifter alerts and assessments.

Recognising the dynamism and diversity of a globalised market, we participate in regional and international harmonisation initiatives for drugs, medical devices and radiation safety as part of our commitment to accelerate product and service development, facilitate trade and public accessibility while tapping on new technical knowledge.

Our involvement in regulatory harmonisation also serves to contribute as a global player and to achieve greater medical, pharmaceutical and radiation safety for Singaporeans.

Besides working actively in a number of ASEAN technical co-operation initiatives involving healthcare products, we are also active in the Global Harmonisation Task Force (GHTF) for the harmonisation of regulatory requirements for medical devices. We currently chair the Asian Harmonisation Working Party, a regional grouping working towards implementing the GHTF consensus and approach in Asia.

In radiation safety, our Centre for Radiation Protection participates in various World Health Organisation (WHO) committees and the International Atomic Energy Agency in global and regional project formulations and standards harmonisation activities.

At the investigative, scientific and analytical front*, the drive to meet our stakeholders' expectations challenges us to strive for benchmarking and international recognition of our standards through formal accreditation exercises.*

Our Centre for Forensic Science (CFS) has successfully achieved the American Society of Crime Laboratory Directors / Laboratory Accreditation Board re-accreditation for another 5 years. This bears testimony to our commitment to provide an internationally recognised forensic science service for the administration of justice in Singapore. Further, in June 01, the United Nations International Drug Control Programme has appointed CFS' Narcotics I Laboratory to be the reference laboratory for analysis of controlled drugs for the seized materials group.

Likewise, our Centre for Analytical Science (CAS), the largest single-site testing laboratory facility, is seeking accreditation by the Singapore Accreditation Council-Singapore Laboratory Accreditation Scheme (SAC-SINGLAS) under the new ISO/IEC 17025 in chemical, biological and environmental testing fields. Our clients therefore can exploit this accreditation strategically for their overseas markets. In addition, CAS' Food Laboratory and Pharmaceutical Laboratory continue to be internationally recognised as WHO Collaborating Centres for Food Contamination Monitoring and Drug Quality Assurance respectively.

I am pleased to highlight that our pursuit of professional excellence has led to the development of a novel system to extract bioactive ingredients from herbal medicinal products using pressurised liquid extraction in a more efficient and cost-effective means than conventional methods. This innovation has been filed for patent protection and holds good prospect for commercialisation.

Strategic alliances leveraging on the strengths of partners serve to enhance our deliverables to our stakeholders.

We maintain strong collaborative partnerships with academia in the Departments of Pharmacology, Pharmacy and Chemistry of the National University of Singapore. In April 01, we formalised our partnership with the Singapore Red Cross Society (SRCS) as the National Blood Donor Recruiter. The tradition of SRCS for volunteerism and humanity and its strength in community outreach and networking will no doubt encourage more Singaporeans to give the gift of life.

Setting standards in transfusion medicine, our Centre for Transfusion Medicine (CTM) is internationally renown for the quality of our blood safety practices, which ensures that more than 64,000 units of donated blood per year are safe for use by patients in our hospitals.

CTM's well documented and high quality work performance standards have been singled out as a national model under the National Model Company Programme by Productivity & Standards Board Singapore (now SPRING Singapore).

Its emphasis on highly sophisticated quality management in all areas of blood transfusion including recruitment of blood donors, testing, processing, production, distribution and use of blood and blood products has been recognised as exemplary by WHO. In FY 02, CTM, already a WHO Collaboration Centre for Transfusion Medicine, has been identified as a regional Quality Management Project training centre of the Western Pacific Region, and will conduct intensive training for many national blood programme officers in the region.

Promoting Innovation and Organisational Excellence

Improving our organisational efficiency is an important step towards moulding HSA into a high-performance outfit.

To chart and catalyse our journey towards organisational excellence, a new Office for **Inno**vation and **Ent**erprise, or in short, In^{2}Vent, was established.

In^{2}Vent led the initiative to implement the use of the Balanced Scorecard (BSC) as a strategic and performance management tool to align operational objectives with our high level mission and vision. Over two days in October 01, a Strategic Review and BSC Retreat was organised for senior management to map the first set of strategic objectives and draft the strategy map for HSA's Scorecard. Roadshows and staff communications built corporate awareness, while 13 BSC Development Teams were formed in the professional centres and corporate departments to encourage staff ownership and participation.

Concurrently, the journey to achieve the People Developer Standard and Singapore Quality Award was commenced. In November 01, our Centre for Analytical Science was the first within HSA to embark on a pilot trial of Business Excellence Assessment for Continuous Improvement to seek the Singapore Quality Class recognition by FY02.

Moving in tandem to serve, not just the ongoing developmental projects, but also the new initiatives and standards arising through all our centres' strategic reviews is the ongoing development of new management systems to harness new knowledge and technology in information management, human resource, finance, corporate services and corporate communications.

Our Commitment

Globalisation and rapid advances in science, medicine and technology will continue to pose many challenges for the future. This first year of consolidation and building on our strengths and capabilities has firmly established the vital foundation for our journey towards regulatory, professional and organisational excellence. In the coming year, we are confident that we can continue to **strengthen** our resilience, **stretch** the reach of our capabilities, and **surmount** the challenges of the day with fortitude. In so doing, we remain committed to achieving our mission to excel in applying science to support healthcare services and regulation, serve the administration of justice and enhance safety in our community.

Dr Clarence Tan
Chief Executive Officer

board members

Chairman
Prof Hang Chang Chieh
Deputy Chairman
Agency for Science,
Technology and Research

Member
Mr Boon Swan Foo
Advisor, ST Engineering Ltd
Executive Chairman
Exploit Technologies Pte Ltd
Managing Director, Agency for
Science, Technology and Research

Member
Dr Arthur Chern
Director
Health Service Development
Ministry of Health

Member
Mr Giam Chin Toon
Senior Counsel
Wee Swee Teow & Company

Member
Mr Khoo Chin Hean
Chief Executive
Energy Market Authority

Member
Prof Edmund Lee
Professor of Pharmacology
Faculty of Medicine
National University of Singapore

Member
Mr Lim Hock San
President & Chief Executive Officer
United Industrial Corporation Ltd &
Singapore Land Ltd

Member
Prof Lim Mong King
Deputy President
Nanyang Technological University

Member
Mr Ng Wai Choong
Director
Enterprise Division
Ministry of Trade and Industry

Member
Mr Stephen Yeo
President &
Chief Executive Officer
Singapore Computer Systems


HSA
Health Sciences Authority
Going The
Extra Mile
for the
Gift of Life

highlights of the year

2001

APRIL

- HSA was established as a new statutory board of the Ministry of Health on 1 April 01. With the launch, a new corporate identity for HSA was unveiled together with its vision, mission and values.
- The Authority set up its Office for Innovation and Enterprise (In^2Vent) with the objectives to drive and co-ordinate innovation and enterprise processes and facilitate the implementation of organisational excellence initiatives.
- CTM formalised its partnership, via a Memorandum of Understanding, with the Singapore Red Cross Society as the National Blood Donor Recruiter.
- CAS' Pharmaceutical Laboratory was re-accredited for another 4 years as a World Health Organisation (WHO) Collaborating Centre for Drug Quality Assurance.
- CFS set up a DNA Database Laboratory in collaboration with the Singapore Police Force.
- CMDR initiated the development of an online Medical Device Register.
- CRP designed the remote radiation monitoring network for MINDEF.
- CFM established key turnaround time for services committed on service level agreements with key stakeholders.

MAY

- CFM initiated a major review of key professional protocols with a re-documentation of major core activities and updated guidelines.

JUNE

- CFS
  - was re-accredited by the American Society of Crime Laboratory Directors / Laboratory Accreditation Board (ASCLD/LAB) for another 5 years.
  - introduced new paternity testing through its DNA Profiling Laboratory.
  - its Narcotics I Laboratory was invited by the United Nations International Drug Control Programme to be a reference laboratory for seized materials.
- CTM won recognition as a national model for its clear work performance standards under the National Model Company Programme by the Productivity & Standards Board (since renamed SPRING Singapore).
- CFM participated in a Zero-IN Process Panel Review chaired by the Ministry of the Environment in reviewing death certification processes so as to provide seamless service to the next-of-kin.

JULY

- The Authority embarked on the quest to attain People Developer Standard certification.
- The Authority started its discussion with the Therapeutic Goods Administration, Australia to enter into a formal collaborative relationship in the form of a Memorandum of Intention of Co-operation.
- CPA
  - implemented the revised guidelines for the review of forensic classification of medicinal products. All stakeholders, including members of the public, may now submit request to the Authority to consider changing the classification of medicinal products.
  - introduced the pilot programme of having 3 differentiated pathways for registration of new drugs in Singapore. Pharmaceutical companies are able to choose the pathway that is most appropriate for their product.
  - initiated the review of the clinical trial regulatory framework with the main objectives of enhancing the safeguards for trial subjects and streamlining the approval process. The review is targeted to be completed by end 2002.
- The Authority embarked on the scheme that trains and deploys CPA officers as prosecutors for routine prosecution cases. The scheme enhances HSA in-house prosecution capability as well as increases productivity.
- The new Medicines Advisory Committee (MAC) was appointed by the Minister for Health to provide advice to CPA and CDE in the pre-market evaluation and registration of medicinal products. The MAC, comprising 14 members, was appointed for a 2-year term from 1 July 01 to 30 June 03.
- The Authority participated in the fund-raising for Chao Tzee Cheng Professorship Ultramarathon.




AUGUST

- The Authority collaborated with the Infocomm Development Authority of Singapore to address the public health and safety concerns of handphone radiation. CRP issued the Health and Safety Guidelines on Electromagnetic Fields and Public Health.
- 28 expert panels, comprising a total of 89 experts, were appointed for a period of 2 years from 1 August 01 to provide specialist advice to HSA and the MAC. In addition, 118 experts were appointed as external evaluators to assist CPA and CDE in the scientific evaluation of safety, quality and efficacy of medicinal products.
- The HSA family celebrated National Day together with activities that encouraged community involvement and supported welfare organisations.

SEPTEMBER

- CPA
  - successfully implemented the third and final phase of Chinese Proprietary Medicines (CPM) control.
  - gazetted the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice (GMP) for medicinal products as the GMP standard for Singapore as HSA is a member authority of PIC/S. The gazette came into operation on 1 September 01.
  - engaged CISCO to conduct inspection of tobacco retailers as well as to enforce the prohibition of smoking by youths under 18 years old.
- CTM initiated the development of guidelines of blood usage for the hospitals in conjunction with Singapore Society of Haematology.
- The Authority, an integral part supporting the growth of biomedical sciences in Singapore, participated as part of the Singapore Pavilion in Biomedical Asia 2001.
- The Authority embarked on its journey towards attaining the Singapore Quality Award with CAS taking the lead.
- The HSA family came together for a brisk walk from its headquarters to Mount Faber to celebrate good health, fun and company on HSA Active Day.

OCTOBER

- The Authority's senior management attended a Strategic Review and Balanced Scorecard Retreat to review the HSA's strategic objectives and develop the strategy map for the corporate scorecard.
- The Authority commenced its first series of "Strategic Thinking @ HSA" lectures that seek to provide avenues for the meeting of minds and to keep all scientific and regulatory professionals abreast of developments in relevant disciplines and global trends.
- The Authority launched its innovation journey via an IDEAS Forum to embrace the innovative character in each staff and to promote innovation and enterprise as part of its work culture.
- CTM hosted the first regional Quality Management Project 3-day introductory workshop for directors of blood transfusion services and national blood programme officers of the Western Pacific Region.
- CRP formalised its participation in the WHO International Electromagnetic Fields Project.

NOVEMBER

- CAS
  - filed a patent on a novel system developed to extract bioactive ingredients from herbal medicinal products using a pressurised liquid extraction method.
  - sought accreditation by the Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme (SAC-SINGLAS) of its 7 laboratories under the new ISO/IEC 17025 in chemical, biological and environmental testing fields.
- CRP
  - hosted a 2-week International Atomic Energy Agency Training Course on Safety Assessment Methodologies for Near Surface Radioactive Waste Disposal.
  - implemented the quality assurance and radiographic standards and procedures in mammography.
- CFM initiated a medical mortality review and carried out regular reviews of all peri-operative deaths.
- The Authority conducted an organisation-wide health screening programme which had high staff participation.

DECEMBER

- CDE received its 2nd funding cycle of $6.8 million for 3 years from the Agency for Science, Technology and Research.
- CAS was invited by WHO to take part in a Proficiency Testing Programme, a new initiative which was open to selected government laboratories.




2002

JANUARY

- The Japan-Singapore Economic Partnership Agreement, which included a Joint Statement on Pharmaceutical Good Manufacturing Practices (GMP) Inspection, was signed by the Prime Ministers of both countries on 13 January 02. The areas of co-operation between HSA and Japan's Ministry of Health, Labour and Welfare included exchange of technical and regulatory information such as GMP inspection reports and classified product recalls.

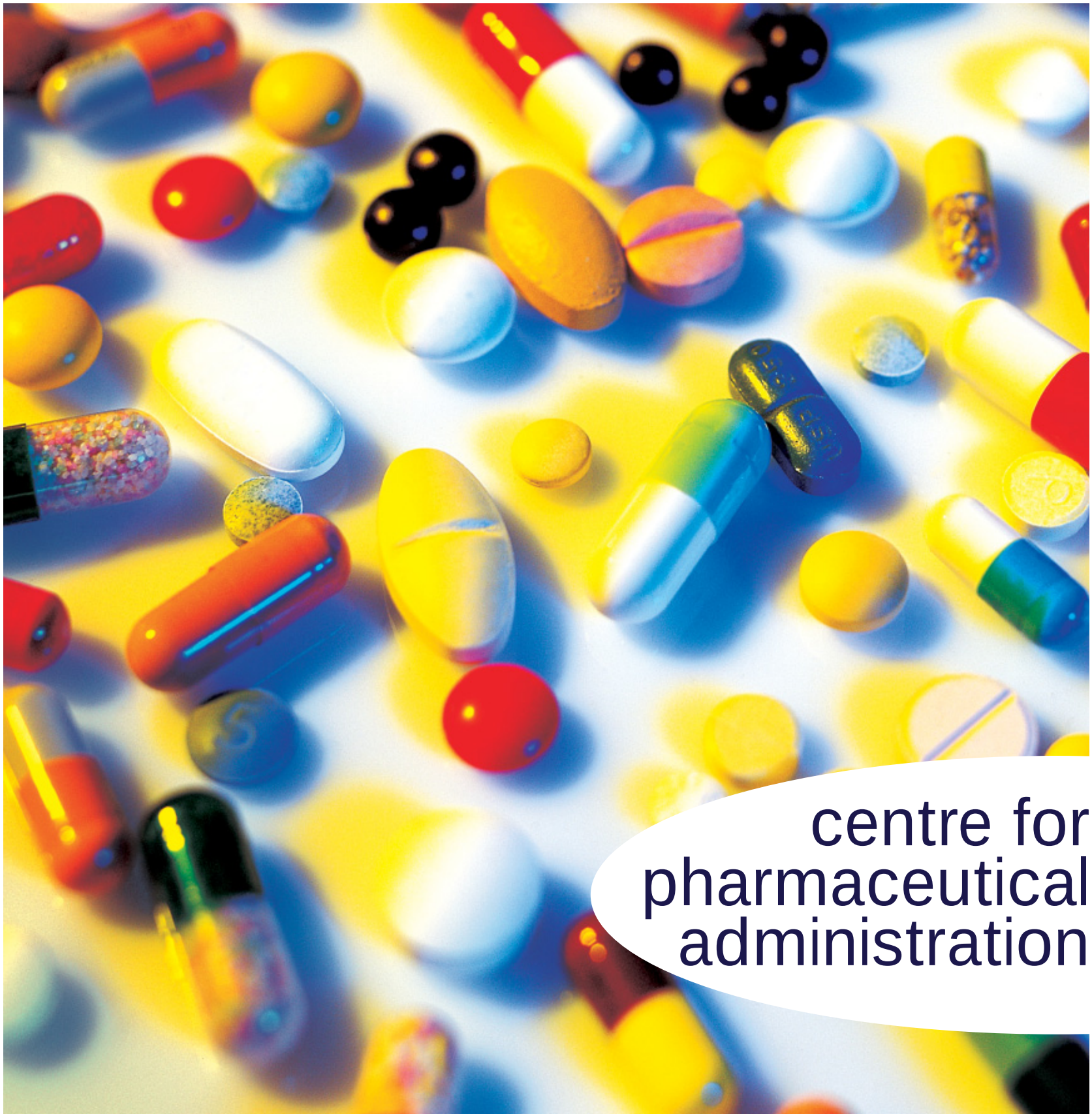
FEBRUARY

- CPA
  - was appointed by the ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group to be the co-ordinator for the development of the ASEAN Guideline for Production Process Validation.
  - was appointed by the ACCSQ Cosmetic Product Working Group to be the lead country in the task of addressing the infrastructural needs in ASEAN countries to conduct safety evaluation and post marketing surveillance of cosmetic products.
  - established a 5-year plan for the development of pharmacovigilance and drug safety monitoring activities in Singapore. The activities in the blueprint will be carried out over the next few years to promote ADR reporting by healthcare professionals and closer monitoring of marketed products to safeguard public health.
- CFS' electronic data transmission system between its Narcotics II Laboratory and the Central Narcotics Bureau was fully established.
- The HSA sports enthusiasts, who competed in various elimination rounds, met at the finals held on HSA Sports Day.

MARCH

- The Authority signed its Memorandum of Intention of Co-operation with Department of Chemistry, National University of Singapore for collaboration in areas of scientific investigations, forensic science and research related to the safety, quality and efficacy of health-related products.
- CPA led a delegation in the first official visit to the State Drug Administration, People's Republic of China, with the objective of enhancing co-operation in the areas of pharmaceuticals, CPM and medical devices.
- The Authority represented Singapore as one of the seven founding members of the Western Pacific Regional Forum for the Harmonisation of Herbal Medicines at its first meeting held in Beijing in March 02. The other founding members include China, Japan, South Korea, Australia, Vietnam and Hong Kong.

- CMDR introduced the voluntary product registration scheme for higher-risk medical devices.
- CTM
  - produced the first batch of Factor IX from donors' plasma to enhance the local supply of high quality blood products at reasonable cost.
  - completed its renovations of a new and fully dedicated state-of-the-art Apheresis Suite@HSA.
- The Authority sponsored the Singapore Science Centre's Omnimax movie "The Human Body" and conducted a series of "HSA Excellence in Applying Science" educational talks on forensic science, forensic medicine, transfusion medicine and pharmaceutical sciences topics to primary, secondary and pre-tertiary students. This was part of the Authority's community outreach initiatives.
- The HSA Family, which turned out in full force with their spouses, children and friends, had great fun and a memorable time at the Siloso Beach in Sentosa to celebrate its first Family Day.



centre for pharmaceutical administration

To safeguard public health and contribute to the development of the biomedical sciences by administering a robust, scientific and responsive regulatory framework, which ensures that pharmaceuticals and health-related products in Singapore meet appropriate standards of safety, quality and efficacy.

Core Functions ▪ Pre-market evaluation and licensing of medicines ▪ Regulation of clinical trials ▪ Good Manufacturing Practice (GMP) audit and certification of GMP international standards ▪ Licensing of manufacturers, importers, wholesalers and retail pharmacies ▪ Regulation of Chinese proprietary medicines ▪ Regulation of health supplements ▪ Regulation of cosmetics ▪ Post-marketing monitoring of safety of licensed products ▪ Administration of adverse drug reaction reporting programme ▪ Regulation of medical advertisements and sales promotions of medicines and health-related products ▪ Investigation and enforcement of legislation governing medicines and health-related products ▪ Provision of unbiased drug information ▪ Pharmacoeconomic assessment and drug utilisation research ▪ Licensing of tobacco product retailers ▪ Enforcement of various provisions in the Smoking (Control of Advertisements and Sale of Tobacco) Act

centre for pharmaceutical administration

The **Centre for Pharmaceutical Administration (CPA)**, one of HSA's 8 centres, was formerly known as the National Pharmaceutical Administration under the Ministry of Health.

As the national regulatory agency for medicines and health-related products, CPA's primary objective is to safeguard public health by ensuring that medicinal and health-related products in Singapore meet appropriate standards of safety, quality and efficacy. Products which are currently being regulated, include western medicinal products, Chinese proprietary medicines, health supplements and cosmetic products. CPA is also responsible for the regulation of clinical trials in Singapore and the provision of unbiased drug information to health professionals and the public. In addition, CPA administers and enforces the Smoking (Control of Advertisements and Sale of Tobacco) Act in support of our government's efforts to reduce the harmful effects of smoking to public health.

Pre-market Evaluation and Licensing of Medicinal Products

CPA carries out pre-marketing evaluation of medicinal products before they are allowed to be marketed in Singapore. Only products that meet the approval criteria of safety, efficacy and quality are granted product licences.

For the period January 01 to March 02, 421 new product licences were issued with the average timeline of 4.4 months. A total of 2,038 product licences was also renewed. Of the 421 new products licensed, approximately 20% are products that contain new chemical entities / new biological ingredients or are products that contain new combinations of existing drugs.

During the same period, 1,122 changes to the product licences were assessed. The major variations included changes of product manufacturer, product formulation, dosing regimens and other labelling changes. In addition, CPA initiated changes to product information leaflets for 42 products as a result of new safety information.

To ensure that medicinal products manufactured in Singapore for exports meet the same criteria for quality, safety and efficacy as those marketed locally, with effect from 1 September 02, products manufactured for exports are required by legislation to be licensed by CPA before they can be exported overseas.

Forensic Classification Review

In response to consumers' expectations to have greater access to medicinal products that can be used safely for self-medication, with effect from 1 July 01, CPA implemented a new system for the systematic review of forensic classification of medicinal products.

In addition to product owners, healthcare professionals and consumers may request for specific products to be considered for reclassification. To facilitate the process, the guidelines for submission of requests have been posted on the website.

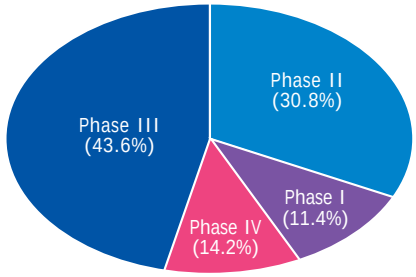
At the end of March 02, there were 7,438 licensed products in Singapore. They were distributed, by the three forensic classifications, as follows:

Forensic Classification	No. of Products	Percentage
Prescription Only Medicines (POM)	5,071	68.2%
Pharmacy Only Medicines (P)	1,059	14.2%
General Sale List (GSL)	1,308	17.6%
Total	7,438	100.0%

Regulation of Clinical Trials

For the period January 01 to March 02, 211 new clinical trial certificates were issued. In addition, another 25 certificates were issued for extension of the trials.

New Clinical Trials Approved in January 01 to March 02



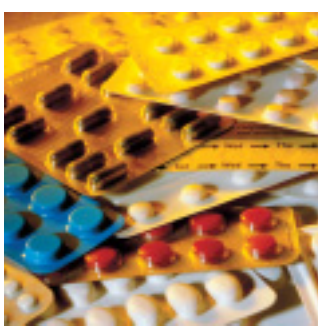
The number of clinical trials being conducted in Singapore has been increasing over the last few years. There is also a significant increase in the number of early phase trials. In view of the need to enhance the safety of trial subjects and to improve the approval process, CPA has embarked on the review of the regulatory framework for clinical trials. The review, which is being undertaken in consultation with the Medical Clinical Research Committee (MCRC) and the Clinical Trials Co-ordinating Committee (CTCC) is targeted for completion at the end of 2002.

Licensing of manufacturers, assemblers, importers, wholesale dealers and pharmacies

125 manufacturers' and assemblers' licences were issued for western medicinal products, Chinese proprietary medicines, cosmetic products and controlled drugs from January 01 to March 02.

During the same period, 300 wholesale dealers' licences and 337 pharmacy certificates were also issued. 530 site inspections were carried out before licences/certificates were issued to ensure that these companies comply with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) standards, legal requirements under the Medicines Act, Poisons Act and the Misuse of Drugs Regulations, as well as Singapore's obligations under the United Nations Conventions on Psychotropic Substances and Narcotic Drugs.

More than 20 different types of licences and certificates were issued including 505 World Health Organisation Certificates of Pharmaceutical Products / Free Sales Certificates, 612 import licences and 109 export licences for psychotropic substances and narcotic drugs and 898 Poisons Licences.



Good Manufacturing Practice

CPA became the 1st Asian member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) with effect from 1 January 00. Subsidiary legislation was gazetted under the Medicines Act to adopt the PIC/S Guide to GMP for Medicinal Products as the GMP standard for Singapore with effect from 1 September 01. At least 15 sets of technical guidance notes, developed in consultation with the HSA Quality Control Advisory Committee, were made available to the industry to facilitate their GMP implementation.

An extensive review and revision of the quality management system to include GDP audit and licensing of importers and wholesale dealers of western medicinal products and Chinese proprietary medicines was conducted.

Regulation of Chinese Proprietary Medicines

The year 2001 saw the full implementation of Chinese proprietary medicine (CPM) control, which was carried out in 3 phases over a span of 3 years since 1999. Following the successful conclusion of the third and final phase of CPM control which took effect from 1 September 01, all CPMs are required to be assessed for safety and quality and meet full labelling requirements before they can be marketed in Singapore. All importers, wholesalers, local manufacturers and re-packers of CPMs must also be licensed. As of 31 March 02, the number of licensed CPM importers, manufacturers, re-packers and wholesale deals stood at 194, 23, 30 and 266 respectively.

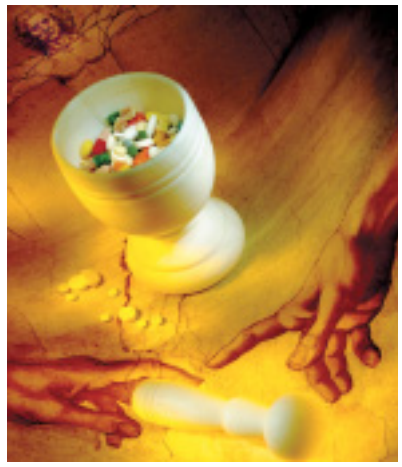
During the period January 01 to March 02, 4,696 applications for CPM product listing were received and 4,196 products were allowed to be listed. As of 31 March 02, 9,149 CPMs were listed.

The adverse effect reports from overseas prompted the review of the control measures for the following herbs: Aristolochia, Radix Trichosanthis and Cortex Magnoliae Officinalis. These reviews, which were carried out in consultation with the CPM Advisory Committee, concluded that the present control measures were adequate.

To enhance the training of Chinese herbal dispensers, CPA facilitated the organisation of the Chinese Medicinal Materials Dispensers Training Course by the Singapore Traditional Chinese Medicine Organisations Committee in consultation with experts from Beijing University of Chinese Medicine. The training plan was endorsed by the Traditional Chinese Medicine Practitioners Board.

Regulation of Health Supplements

Currently health supplements are not subject to any licensing or pre-marketing assessment before they can be sold locally. Health supplement dealers must not contravene the legislation governing medicinal products especially the Medicines Act, the Poisons Acts and the Medicines (Advertisement & Sale) Act.



A set of guidelines pertaining to the import, sale and advertisement of health supplements was distributed to inform the trade of the current legislative controls imposed on health supplements. The guidelines were posted on the website in January 02.

The development of a specific framework for the regulation of health supplements was initiated and targeted for implementation in 2003. While the framework was being established, an enquiry service was established to handle enquiries related to health supplements from the trade and the public. A total of 3,769 enquiries was handled in FY 01.

To ensure that unsafe products were promptly removed from the market, CPA closely monitored the reports of adverse reactions associated with health supplements. In FY 01, adverse reactions arising from the following products were investigated: products containing kava-kava, the weight-loss supplement Lipokinetix and a Jamu product known as Serbuk Jarem (Encok). Appropriate regulatory actions were subsequently taken to remove these products from the market to protect public health and safety.

Regulation of Cosmetics

In FY 01, 13,794 cosmetic product licences were issued. These included new cosmetic product licences, renewed licences and amended product licences. During the same period, 277 import licences were issued.

The classification status of hair-dyes containing diamines was reviewed with the objective of making hair-dyes more accessible to consumers. The review resulted in the reclassfication of hair-dyes containing diamines as Category 1 cosmetic products, with effect from July 01. As cosmetic products, they can be sold in all retail outlets after they have been assessed and licensed.

Safety Monitoring of Medicinal Products

CPA continues to monitor the safety of medicinal products after they have been licensed for marketing in Singapore. Healthcare professionals are encouraged to report suspected adverse drug reactions (ADRs) to CPA's Pharmacovigilance Unit. All ADRs reported are assessed and captured into an ADR database which allows for further analysis of these important signals.

As a result of the enhanced efforts to encourage healthcare professionals to report ADRs, a record number of ADR reports was received. Approximately a quarter of the 609 reports submitted comprised serious ADRs. These serious ADRs were investigated further to assess whether any regulatory actions would be required to address any safety concerns.

During the year, doctors and pharmacists in Singapore were alerted to the serious ADRs associated with allopurinol and kava-kava containing products which were marketed as health supplements. Two issues of ADR News were also published to highlight ADRs of current drugs as well as case reports of serious ADRs. The publication, which has received positive feedback from healthcare professionals, will continue to be HSA's important communication channel with healthcare professionals in Singapore to enhance drug safety in our community.

Regulation of Medical Advertisements and Sales Promotions

CPA regulates medical advertisements and sales promotions for medicinal products to ensure that the information presented to the public is accurate and not misleading. Such medical advertisements are carefully screened before permits are issued. In FY 01, 1,445 permits for advertisements and sales promotions were issued.

As a result of a policy review, advertisements of rubber condoms no longer required permits from CPA with effect from February 02. Permit holders were informed of the change and advised to contact relevant authorities on matters concerning advertising of condoms.

Investigation, Surveillance and Prosecution

All complaints and feedback from the public on any medicinal products are investigated. From January 01 to March 02, 188 complaints from various sources were investigated.

In collaboration with national and international enforcement agencies, 26 products, including CPMs, were found to be adulterated with sildenafil. 5 of these products were imported and sold in Singapore, while the others were detected before entry into Singapore. The parties responsible for the 5

adulterated products were prosecuted and the adulterated goods with a street value of $600,000 were seized.

During the same period, 17 cases were prosecuted in Court resulting in a total of $150,700 in fines imposed on 38 charges under the Poisons Act, and a case with a 10-week imprisonment term. 141 compositions were issued under the Medicines Act for a total of $109,150 in composition fines.

The indiscriminate sale of cough mixture containing codeine was another focus area targeted for enforcement during the year. An undercover operation resulted in the conviction of a registered pharmacist. A number of joint operations was also conducted with the Singapore Immigration and Registration, Singapore Police Force and Central Narcotics Bureau to bust illegal operations which involved organised groups of immigration offenders.

Other enforcement activities carried out included a case of arrest for the sale of Wei Ge Wang, a product containing sildenafil and one company was compounded for making medical claims on a health supplement product, Elixir Youth Enhancing Formula 1.

To detect illegal sale of medicinal products over the internet, the local websites offering health products for sale are routinely monitored and screened. Through the routine surveillance of the internet and subsequent investigation, an elusive case of illegal sale of prescription drugs, including Viagra®, on 3 internet auction websites, was successfully cracked. The auction pages on the websites involved were removed, and the illegal vendor was subsequently charged under the Poisons Act.

Tobacco Regulation

During the mass renewal exercise in August 01, 4,550 tobacco retailer licences were renewed. As of March 02, there were 7,576 tobacco retailers in Singapore who had been issued with the required licences. In FY 01, 40 retailers were caught selling cigarettes without valid licences and appropriate enforcement actions were subsequently taken against them.

CPA continues to intensify its enforcement efforts to prohibit smoking by youths under 18 years old. The increased surveillance resulted

in 1,761 under-aged youths being caught for smoking or possession of cigarettes. 873 of these young offenders were compounded while 124 were prosecuted in court.

Cigarettes on sale in the market are routinely sampled for testing of tar and nicotine contents. During the year, 386 cigarette samples were sampled and tested. Through the routine testing programme, cigarettes sold in Singapore were found to have 99% compliance rate to the legal limits of tar and nicotine contents.

Regular Dialogues with Industry and Healthcare Professionals

To nurture understanding and co-operation of our stakeholders from the industry, CPA senior officials held regular dialogue sessions and meetings with the key associations representing their respective sectors of the pharmaceutical and therapeutic goods industry, namely, Singapore Association of Pharmaceutical Industries, Singapore Pharmaceutical Manufacturer's Council, Singapore TCM Organisation Committee, Association of Perfumes and Cosmetic Distributors, and Health Supplement Industry Association.

CPA also initiated communications with the Singapore Medical Association and the Pharmaceutical Society of Singapore as and when necessary to seek comments or inputs from the relevant healthcare professionals.

International Co-operation and Harmonisation Projects

To maximise Singapore's limited resources and contribute to the development of drug regulation internationally, CPA values co-operation and collaboration with other drug regulatory authorities and other scientific agencies both locally and overseas.

As a member of the pharmaceutical product working group and cosmetic product working group appointed by the ASEAN Consultative Committee for Standards and Quality, CPA was actively involved in the following ongoing technical co-operation projects:

- ASEAN Harmonisation of regulatory requirements for drug registration
- ASEAN Harmonisation of standards and regulatory requirements for cosmetic products

In the area of GMP and quality audits, a Joint Statement on Pharmaceutical Good Manufacturing Practices (GMP) Inspection was included in the Japan-Singapore Economic Partnership Agreement signed by Singapore and Japan in January 02. Under this agreement, CPA looks forward to closer co-operation and increased information exchanges in the area of GMP and defective product recalls with Japan's Ministry of Health, Labour and Welfare.

As a member of the Permanent Forum on International Pharmaceutical Crime, whose members comprise regulatory agencies from developed countries like USA, UK, Australia as well as the World Health Organisation and Interpol, CPA has been able to establish information exchange linkages with the enforcement agencies of these countries.

To foster closer co-operation with the State Drug Administration of China (SDA), a CPA delegation made a significant formal visit to SDA in March 02 to explore the feasibility of establishing a formal framework for future collaboration with SDA, especially in the area of Chinese herbal medicines.

In addition, CPA represented Singapore as one of the 7 founding members of the Western Pacific Regional Forum for the Harmonisation of Herbal Medicines (FHH), which also includes China, Japan, South Korea, Australia, Vietnam and Hong Kong. The FHH seeks to provide technical guidance on the harmonisation of regional standards and regulation of herbal medicines.

Training & Development

In addition to ongoing centre- and division-level lectures and workshops where specialised training sessions were conducted, professional staff were given opportunities to make study visits to overseas regulatory agencies. Many officers attended overseas conferences and meetings to keep in touch with the latest international developments.

Two professional staff of CPA were awarded the Health Manpower Development Programme Awards for training attachments at the Office of Complementary Medicines, Therapeutics Goods Administration, Australia and at the Drug Information Management, Food and Drug Administration, USA.

The Year Ahead

Looking ahead, CPA will continue to review and make improvements to the drug evaluation and licensing system to provide differentiated pathways for the evaluation and approval of medicinal products without compromising safety, quality and efficacy of the products. The framework for the regulation of clinical trials will also be reviewed and strengthened to ensure that clinical trials conducted in Singapore are of high standards. The reviews of regulatory frameworks and processes will be benchmarked against international best practices.

To facilitate the licensing processes, CPA will embark on the development of a fully integrated computer system to provide for electronic on-line submission. The electronic licensing system will be developed in phases over the next 2 years.

As mapped out in the 5-year blueprint for the enhancement of the pharmacovigilance activities in Singapore, CPA will continue to improve ADR reporting rates and quality of reports, strengthen the evaluation and investigation of serious ADRs and improve communication of safety issues to healthcare professionals.

In the areas of GMP, CPA will continue to recruit and train GMP auditors especially in the specialised areas of manufacturing of biological products and biotechnology products. More technical seminars and workshops will be organised to facilitate GMP implementation by local manufacturers.

In order to further strengthen CPA's internal core capabilities and competencies to meet future challenges ahead, the development and training of its professional and scientific staff remain CPA's key priority in the coming year. CPA will continue to pursue closer co-operation with overseas benchmark agencies.


centre for
drug
evaluation

To critically assess new therapeutic substances in accordance with international practice in a timely and responsive manner to assure their efficacy, safety and quality for marketing authorisation.

Core Functions ▪ Full dossier evaluation of new chemical entities according to international standards ▪ Pre-submission consultations during the various phases of drug development to ensure regulatory compliance ▪ Training for evaluators in drug regulatory science.

centre for drug evaluation

The **Centre for Drug Evaluation (CDE)**, one of HSA's 8 centres, is an integral part of the infrastructure to develop Singapore as a regional medical hub and as a world hub for life sciences research and development.

Funded by the National Science and Technology Board (since renamed the Agency for Science, Technology and Research) through its Biomedical Research Council, CDE's second funding cycle comprises $6.8 million for the period 1 December 01 to 30 November 04.

CDE complements the regulatory role of CPA in drug regulation through its primary focus on the evaluation of new drugs not previously approved in other countries. The presence of this regulatory capability will help to encourage the pharmaceutical industry to grow its research and development in Singapore and make Singapore the country of origin for new and innovative drugs.

In addition, through the development of this regulatory capability, CDE, together with CPA, facilitates the timely introduction and availability of new and innovative quality medicines in Singapore and the region, including medicines targeted for diseases prevalent in the region.

CDE aims to complete evaluations within timelines similar to those of benchmark regulatory agencies such as the US Food and Drug Administration (FDA), the European Agency for the Evaluation of Medicinal Products (EMEA), the UK Medicines Control Agency (MCA), and the Therapeutic Goods Administration (TGA) of Australia.

New Drug Applications

In 2001, CDE received 9 New Drug Applications for assessment bringing the total number of products evaluated since its inception in 1998 to 18.

Panels of Experts

CDE revised and expanded its 3 panels of experts in pharmaceutical chemistry, pharmacotoxicology and clinical disciplines to comprise 180 scientists and clinicians from local universities, hospitals and research institutes. They constitute the main source of external experts that CDE draws upon in the conduct of drug evaluation while continuing to build its in-house drug evaluation capabilities. CDE is also prepared to engage relevant overseas experts where appropriate.

Building Rapport with the Industry

To build good client rapport, CDE held a total of 19 meetings with the pharmaceutical industry and 15 meetings on Pre-Submission / New Drug Application consultations.

For the first time, CDE conducted post-regulatory decision meetings and scientific discussions with industry on products evaluated. Engaging the respective companies' overseas experts in discussions, the meetings provided avenues for the clarification of issues and improved communication with industry players.

Strategic Review Workshop

To map out CDE's future directions, a strategic review workshop, facilitated by the Prime Minister's Office's Scenario Planning Office, was held on 24 October 01. Participants comprised officers from CDE, CPA, In^{2}vent and visiting specialists.

Training & Development

3 in-house training seminars on honing regulatory evaluation competency were organised for CDE's professional staff, CPA's regulatory staff and external evaluators. Key CDE personnel also attended an Asia Pacific Economic Co-operation (APEC) symposium on bridging studies held in Taipei from 25 to 26 May 01, as well as an Asia-Pacific Clinical Trials Conference held in Kuala Lumpur from 24 to 26 September 01.

The Year Ahead

In the coming year, CDE aims to build its capability in the regulatory evaluation of biologicals as well as provide inputs to the professional and scientific regulation of early phase clinical trials. CDE is exploring the feasibility of electronic submissions of new drug application dossiers.

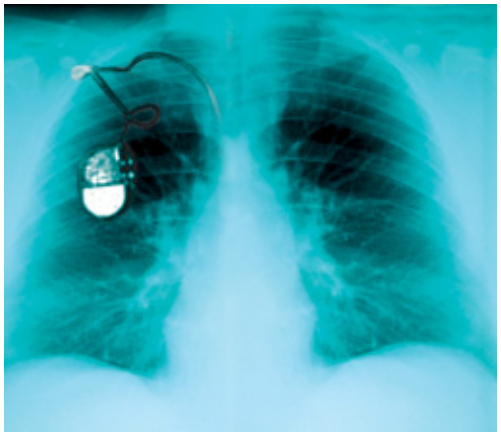
centre for medical device regulation

To ensure that medical devices meet the requirements of safety, efficacy and quality so as to protect public health and safeguard the interests of the patients and users.

Core Functions ▪ Regulation and monitoring standards of medical devices ▪ Registration of contact lens practitioners including the regulation of standards of practice ▪ Participation in international harmonisation initiatives for medical device regulation.

centre for medical device regulation

The **Centre for Medical Device Regulation (CMDR)** is a new regulatory centre established under HSA to spearhead the administration and development for the regulatory control of medical devices in Singapore. Incorporating the former Product Regulation Department of the Ministry of Health, CMDR is developing the regulatory framework for the safety, quality and efficacy of medical devices, which is planned for progressive implementation.



The Centre also administers the Contact Lens Practitioners Act through the registration and licensing of contact lens practitioners and the enforcement of the Act and regulations. As of 31 March 02, there were 409 licensed contact lens practitioners.

A New Framework

A comprehensive review of the regulatory framework for healthcare products has been initiated to consolidate the laws governing medicines and health-related products, including medical devices, under HSA's review.

The medical device regulation, control measures and procedures to be implemented in early 2003 have been designed to be forward–looking to keep pace with global trends in the control of the availability and safety of medical devices.

The regulatory system and regulatory decisions will ensure that beneficial new technologies are made available to patients, consumers and the clinical community in Singapore expeditiously while preventing unsafe or ineffective devices from reaching the market.

Regular Dialogue Sessions

CMDR holds regular dialogues and consultations with local distributors and manufacturers of medical devices which includes updating of pending regulatory changes of control of medical devices on an ongoing basis. Furthermore, the Technical Workgroup, which comprises interested stakeholders from the medical device industry and hospital institutions, has been contributing to develop the medical device regulations.

Voluntary Product Registration

A key initiative of CMDR is the introduction of a voluntary product registration scheme for higher-risk medical devices. It will serve as an interim measure while transiting to the regulated environment. This interim phase will allow for a period of confidence building where one learns about certain levels of regulatory controls; and it offers stakeholders a learning experience and an opportunity to address issues that are obstacles to the path to market for devices.

Singapore Medical Device Register

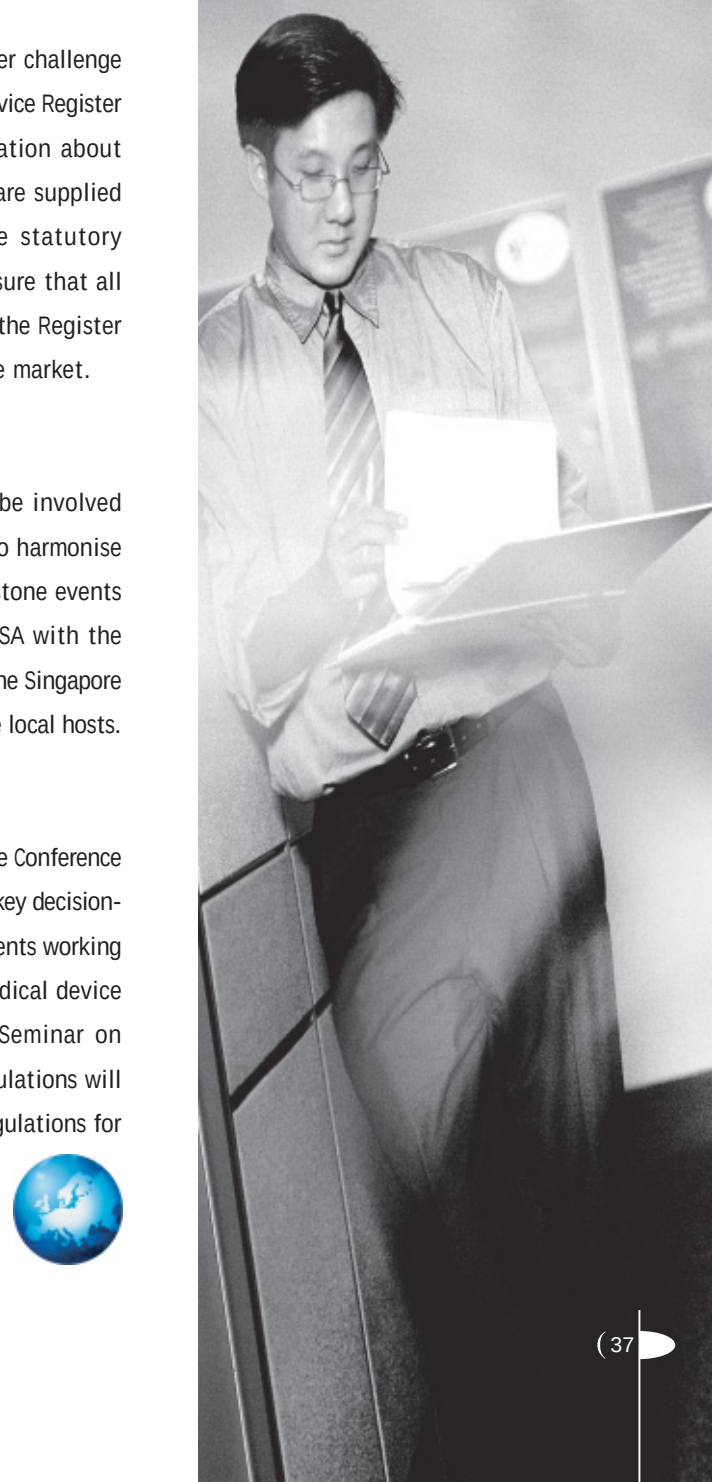
The development of an online Singapore Medical Device Register to capture database information on devices and establishments and listing of available higher-risk devices is another challenge to undertake. The Singapore Medical Device Register is the computer database of information about medical devices for human use that are supplied in Singapore. By 2003, it shall be statutory requirement for manufacturers to ensure that all their medical devices are included in the Register before being placed on the Singapore market.

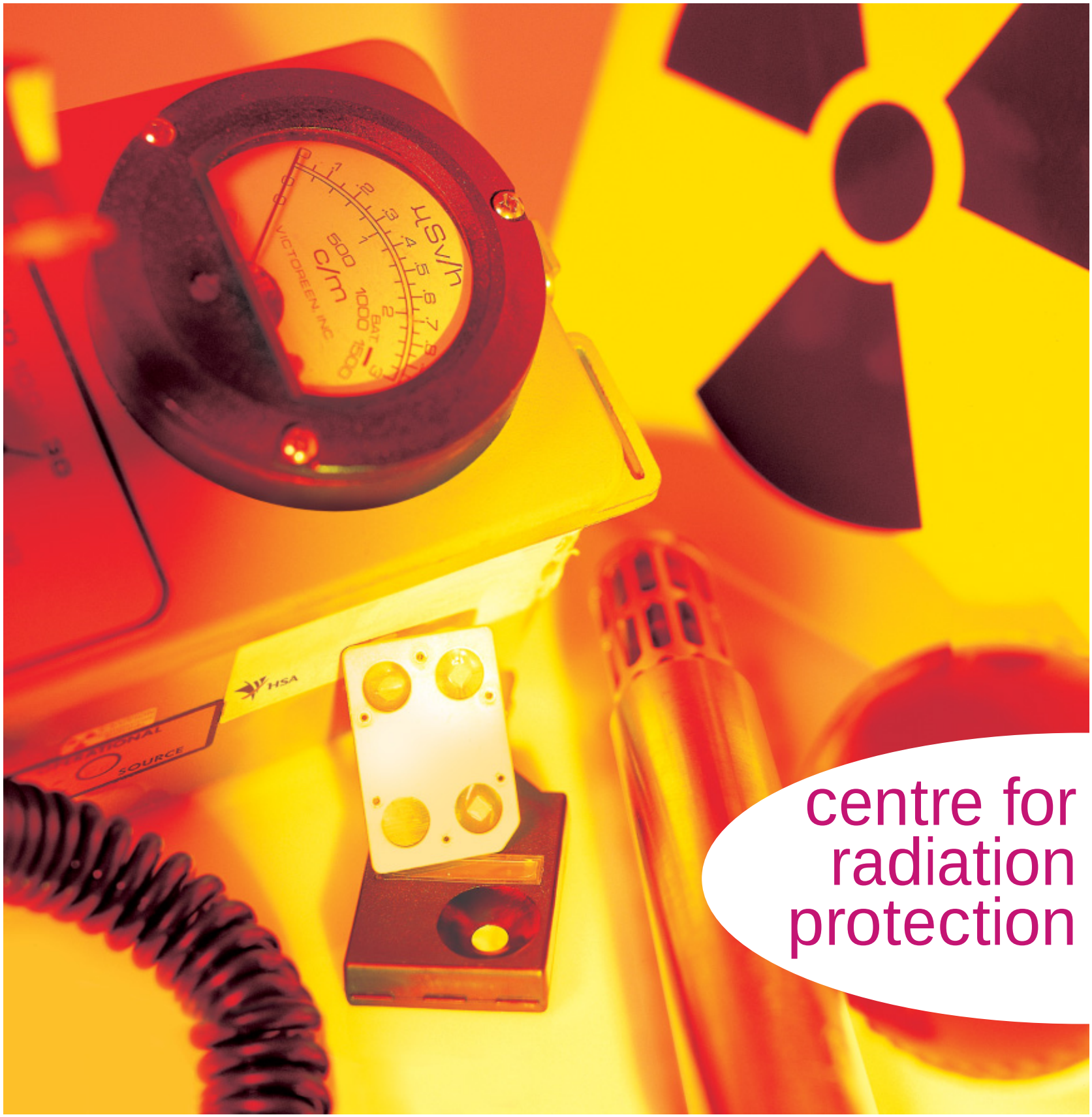
Harmonisation Initiatives

Moving forward, CMDR continues to be involved in regional and international efforts to harmonise medical device regulations. Two milestone events will be held in Singapore in which HSA with the Medical Technology Industry Group of the Singapore Confederation of Industries, will be the local hosts.

The Year Ahead

The 9th Global Harmonisation Task Force Conference in May 2002 will see a congregation of key decision-makers from the industry and governments working towards greater harmonisation of medical device regulatory systems. The 2nd APEC Seminar on Harmonisation of Medical Device Regulations will provide training on medical device regulations for APEC member economies.





centre for radiation protection

To excel in radiation science so as to:

- enforce and promote the radiation safety of workers, the public and the environment;
- ensure that irradiating apparatus and nuclear materials meet the statutory requirements of quality, safety and efficacy.

Core Functions ▪ Regulation of use of ionising and non-ionising radiation equipment ▪ Personal radiation monitoring for all radiation workers ▪ Testing of imported food for radioactive contaminants ▪ Testing of sealed radiation sources for leakages and calibration of radiation measuring instruments ▪ Technical support for the emergency and preparedness planning for dealing with radiological accidents on site or at a national level.

centre for radiation protection

The **Centre for Radiation Protection (CRP)**, which incorporated the Radiation Science Division of the former Institute of Science and Forensic Medicine, is the national controlling authority for the safe use of ionising and non-ionising radiation in Singapore.

It administers and enforces the Radiation Protection Act and its subsidiary regulations through a system of licensing and inspection. Services provided through CRP's 7 laboratories include personal monitoring for all radiation workers, testing of imported food for radioactive contaminants, testing of sealed radiation sources for leakages and calibration of radiation measuring instruments. Its import/export licences and endorsements are auto-processed through the TradeNet System.

Ionising Radiation Control

In FY 01, a total of 13,422 licenses was issued for the purposes of import, export, sale, possession and use of ionising radiation (IR) irradiating apparatus and radioactive materials and the transport of radioactive materials.

1,232 endorsements were given for the import/export of components of irradiating apparatus without the radiation emitting components. 78 endorsements were made for ships carrying nuclear consignments such as nuclear fuel rods, uranium hexafluoride with natural uranium or enriched uranium to transit in Singapore.

Routine inspections for radiation leakages and safety of operation were also conducted at premises using IR irradiating apparatus or radioactive materials. A total of 397 inspections was made at medical, dental and veterinary practice premises and industrial and educational institutions. Checks were performed to assess that the facilities and equipment were in proper condition and that radiation levels at places accessible to public were within limits specified in the Regulations.

Non-Ionising Radiation Control

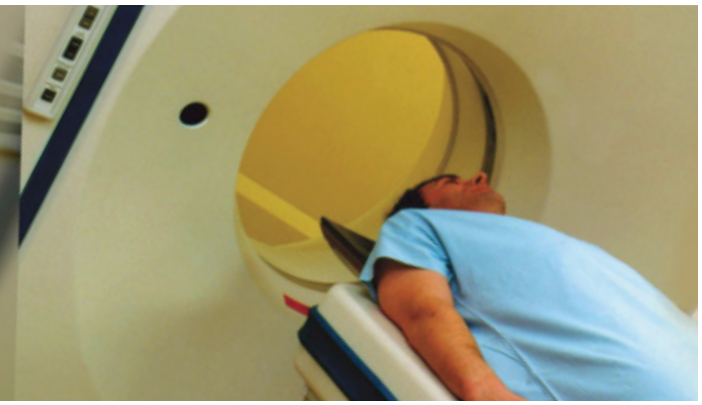
7,427 licenses were issued for the import, export, sale, possession and use of non-ionising radiation (NIR) apparatus in FY 01. The types of NIR apparatus range from magnetic resonance imaging, ultrasound and lasers for industrial, medical and entertainment purposes, microwave oven and UV sun tanning lamps.

66 inspections of premises using NIR apparatus were conducted to ensure that the regulations were compiled with. In addition, 21 surveys at base-stations and radio/television transmitting stations were conducted.

Checks were also performed on 47 new models of microwave ovens to ensure that radiation levels emitting from microwave ovens sold in Singapore were below that specified in the Regulations. Further, all import consignments of laser pointers were checked for the manufacturer class and proper labelling.

Services and Consultancy

In 2001, there were 470 wipe tests conducted at establishments that used sealed radioactive sources in industrial, medical and research



applications. Wipe samples were brought back to CRP's laboratory and tested for presence of radioactivity using NaI and GM detectors.

CRP provided the necessary personal monitoring service to all workers performing ionising radiation work in Singapore. Over 5,000 thermoluminescence dossimeters, or TLDs, were processed monthly. Dose reports were generated and issued to the companies on the level of radiation dosage received by their workers. CRP investigated 46 overdose cases which occurred mainly in the industrial radiography.

98 consultancy services on all aspects of ionising and non-ionising radiation protection were provided to industries, ministries, statutory boards, hospitals and the general public. The services covered a wide spectrum from radioactive waste management system, radiation accident procedures, building design of radiation facilities to measurement of radiation levels in premises and around equipment. One highlight was the successful design of the remote radiation monitoring network for MINDEF.

Lectures and training were also provided for medical doctors, dentists, undergraduates and radiation workers in hospitals, universities and commercial companies. In 2001, 225 tests were conducted to ascertain the workers' competency prior to the issue of licence.

Ionising Radiation Dosimetry

In CRP, its Secondary Standards Dosimetry Laboratory (SSDL) was established with the support of the International Atomic Energy Agency (IAEA) and the World Health Organisation (WHO) as part of the international network of secondary reference laboratories. SSDL acts as a national reference centre for radiation protection and enviornmental dosimetry. Inter-comparisons to ensure accuracy of measurement of radiation dose among participating countries were periodically conducted by IAEA, and the results obtained by CRP were well within acceptable limits.

In 2001, the reference dosimeters maintained by CRP calibrated a total of 353 radiation devices comprising 305 survey meters and 48 quartz fibre electrometers (QFEs) used by companies and hospitals in Singapore.

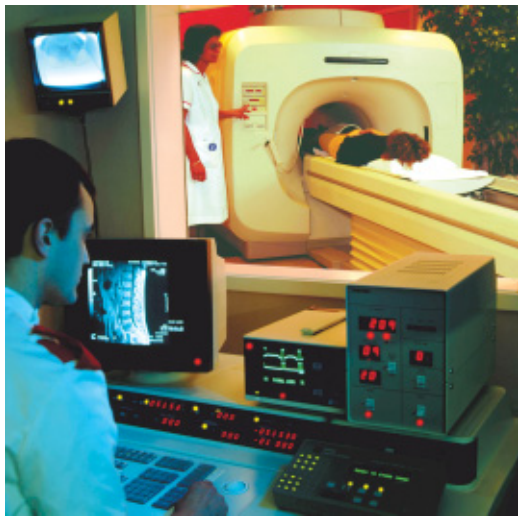
Nuclear Safety and Emergency Planning

During the visits of Nuclear Powered Warships (NPWs), CRP conducted environmental gamma ray monitoring and provided contingency support in the event of a radiological accident. In addition to the monitoring station installed at Sembawang Wharves, another monitoring system was being installed at the new Changi Navel Base. In 2001, 11 NPWs visited Singapore.

Environmental Radiation & Radioactive Waste Management

CRP was constantly engaged in the measurement of radioactivity in environmental samples such as air filters, water and soil, and industrial samples such as ilmenite sands, copper and tin slags, garnet grains, steel rebars, marble, etc.

NaI detectors were also used to conduct radioactivity analysis on food samples. A total of 1,355 food samples was tested and certified free from radioactive contaminants.



International Collaboration

CRP formally participated in the WHO International Electromagnetic Fields (EMF) Project. Further, in response to public concerns on the health risks associated with radiation from mobile phones and base stations, CRP published the Health and Safety Guidelines on EMF exposure.

CRP was honoured to be recognised by the IAEA as a regional training centre for fellows. Under the Singapore-IAEA Memorandum of Understanding signed in 2001, CRP hosted a 2-week IAEA Training Course on Safety Assessment Methodologies for Near Surface Radioactive Waste Disposal from 26 November to 7 December 01. There were 22 participants from 17 member countries, and CRP also provided radiation safety training to fellows from Bangladesh, Jordan, Myanmar and Vietnam.

Quality Assurance & Standards

CRP implemented the quality assurance (QA) and other radiographic standards and procedures in mammography.

The Year Ahead

In the year ahead, CRP will be incorporating mammography QA requirements under the Radiation Protection Regulations. In addition, the Centre will undertake the formulation and drafting of the EMF Regulations as well as the Composition of Fines Regulations under the Radiation Protection Act. Another strategic area of focus will be the education and training of industrial radiographers and dental assistants on radiation safety.

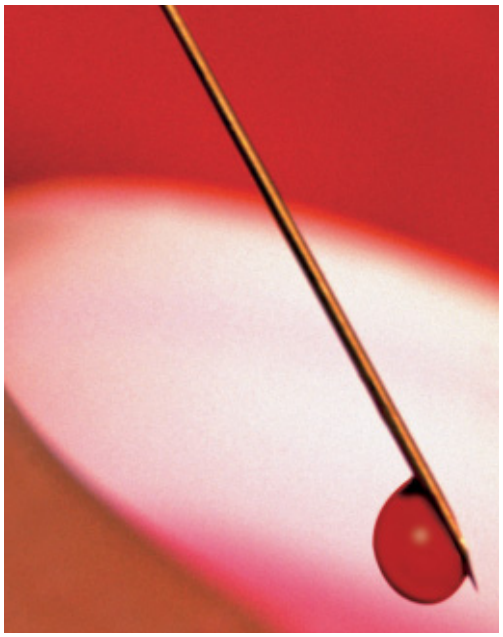
centre for transfusion medicine

To excel in transfusion medicine to:

- ensure a safe and adequate national supply of blood and blood products;
- ensure the appropriate use of blood and blood products;
- provide high quality blood banking services.

Core Functions ▪ Transfusion medicine consultation and blood banking services ▪ State-of-the-art testing for infectious diseases in blood and blood products to ensure the highest standards of blood safety ▪ Management of a comprehensive blood collection centre with an apheresis programme ▪ Provision of outdoor mobile blood collection ▪ Immunohaematology laboratories which provide a wide range of specialised immunohaematological services.

centre for transfusion medicine



The **Centre for Transfusion Medicine (CTM)**, one of HSA's professional centres, was formerly known as the Singapore Blood Transfusion Service. Housed in the HSA building is the Bloodbank@HSA, the largest blood donation suite in Singapore with state-of-the-art equipment and technology.

CTM is responsible for ensuring an adequate and safe national blood supply. It is the primary national agency involved in the collection, processing and distribution of blood and blood components to all public and private hospitals in Singapore.

As a WHO Collaborating Centre for Transfusion Medicine, CTM contributes to improving the standards and practice of transfusion medicine and promoting blood safety and quality in the Western Pacific Region. It has also won recognition as a national model for its clear work performance standards under the National Model Company Programme by Productivity & Standards Board Singapore (since renamed as SPRING Singapore).

In FY 01, CTM collected a total of 64,254 whole blood donations from 41,842 donors. These collections were processed into 170,442 blood components, and 143,798 units were used by the hospitals. A total of 5,430 apheresis procedures was also carried out. Further, CTM performed 675,417 laboratory tests to screen all blood donations for transfusion transmittable diseases like Human Immunodeficiency Virus (HIV) infection, Hepatitis B, Hepatitis C and Syphillis.

International Collaboration

CTM hosted the inaugural WHO Meeting on Quality Management Project for Blood Transfusion Services in the Western Pacific Region from 8 - 10 October 01. Attended by blood bank directors and other key senior health officials from the region, the meeting focused on building regional and national capacity in the area of quality management for all aspects of blood transfusion services.

Local Supply of Factor IX

In addition to Factor VIII, CTM produced the first batch of Factor IX, about 2,200 vials, from donors' plasma to enhance the local supply of high quality blood products at a reasonable cost. Progressive efforts would be made to enhance the local supply so that haemophiliac patients would not need to depend on overseas supply of these essential clotting factors.

Guidelines on Blood Usage

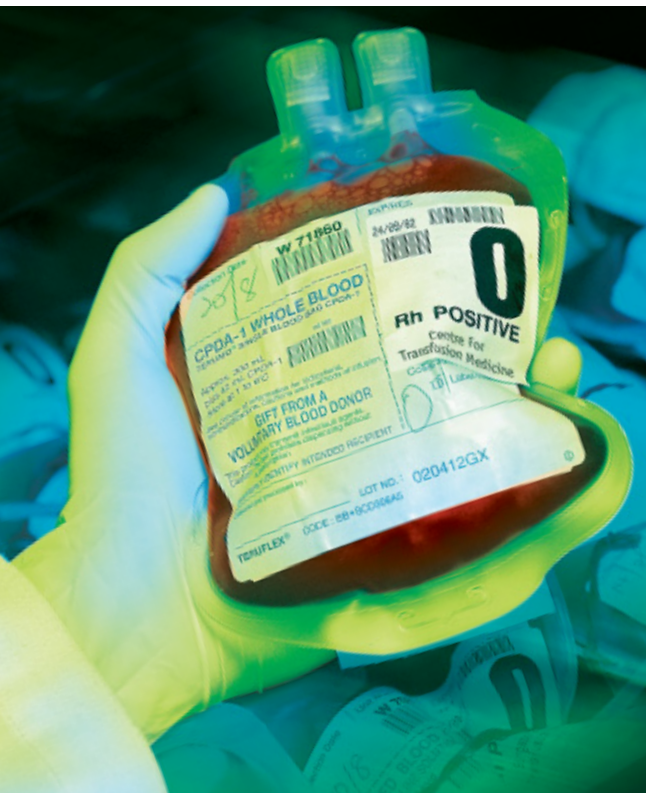
In conjunction with Singapore Society of Haematology, CTM initiated the development of guidelines on the blood usage for the hospitals. The guidelines would be published in FY 02.

Improved Techniques

CTM replaced the manual technique with the implementation of the use of electronic blood bag tubing strippers to improve operational collection of blood samples. It also implemented the enhanced version of HIV-1/2 antibody tests, incorporating improved detection of HIV type 1 group O infection.

National Blood Group Proficiency Testing Programme

CTM conducted 3 exercises on the national blood group proficiency testing programme for 30 laboratories and the pre-transfusion proficiency testing programme for 7 hospital laboratories. These exercises were intended to provide a national external quality assessment to compare inter-laboratory proficiency and identify any weaknesses or problems in the ABO and RhD typing in Singapore.



Apheresis Suite@HSA

CTM completed its renovation of a new and fully dedicated state-of-the-art Apheresis Suite@HSA. To be launched in April 02, the suite would provide a more comfortable and relaxed environment for its regular donors, where each could also enjoy his/her personal choice of the latest movies and full terrestrial networks via the individual TV monitor attached to each apheresis donation couch.

Strategic Alliance with the Singapore Red Cross Society

In April 01, CTM formalised the partnership with the Singapore Red Cross Society (SRCS) as the National Blood Donor Recruiter. SRCS' emphasis on volunteerism and humanity and its strength in community outreach and networking would enhance the blood donor recruitment and retention programme.

Outsourcing of Fringe Operations

Since December 01, CTM engaged a dedicated food caterer to provide donors with a wider and improved range of healthy refreshments after blood donation. CTM also outsourced its operational management of its stores and mobile logistics required for its mobile blood donation drives.

Training and Development

CTM completed research projects on the characteristics of different apheresis machines, viral testing in donors for HTLVI and donor deferral policy.

5 visiting consultants from Mount Elizabeth Medical Centre, National University Hospital, Tan Tock Seng Hospital and Singapore General Hospital were appointed for their professional expertise and advice on service improvement, research and staff education in the field of transfusion medicine and infectious diseases screening.

The Year Ahead

In the continuous quest for excellence, CTM will be seeking international accreditation of its Bloodbank@HSA by the American Association of Blood Banks, a world renowned body in blood banking.

Plans in the pipeline also include the progressive expansion of its autologous and apheresis programmes. Besides, CTM will introduce a pilot project of a national haemovigilance system in August 02.

In the area of donor recruitment strategy, CTM will continue to work in partnership with SRCS to implement the new strategy specifically targeted at tertiary educational institutions.

As part of the commitment to quality donor care, donors can also look forward to a more conducive donation environment as the whole blood donation areas will be upgraded, and e-services provided by the upgrading of the blood bank IT systems.

In its ongoing professional development, new research projects such as assays in platelet serology, assessing the frequency of bacteria contamination in the blood products and new apheresis techniques will be initiated.

centre for forensic medicine

To excel in applying forensic medicine and related sciences to:

- serve law enforcement and the administration of justice;
- support healthcare services, medical audit, medical education and health regulation;
- enhance safety in the community.

Core Functions ▪ The conduct of medico-legal autopsies and scene-of-crime investigations for homicides and suspicious deaths ▪ Provision of medico-legal expertise for the administration of justice ▪ Provision of consultation for clinical medico-legal cases ▪ Postgraduate training in forensic medicine accredited by the Royal College of Pathologists of Australia ▪ Certification of deaths due to natural disease occurring at home.

centre for forensic medicine

The **Centre for Forensic Medicine (CFM)** supports the police and the Coroner for the investigations of deaths that occur suddenly without a known cause of unnatural or suspicious circumstances. CFM provides forensic pathology consultancy services in the determination of cause of death, as well as clinical forensic medical consultations in living victims of violence, such as in spousal abuse, child abuse and sexual offences.

A death certification service is provided to the public through the Police for deaths due to natural causes. CFM acts as an authorised agent of the Registry of Births and Deaths in offering death registration services for Coroner's cases.

It works with the Ministry of Health in the domain of medical audit in the area of post-operative deaths. Consultancy services are also offered to private clients in forensic services and DNA profiling.

In 2001, CFM handled a total of 2,052 post-mortem cases and 474 clinical forensic medicine cases, and its Forensic Death Investigator attended to 400 cases.

Major Re-organisation

To provide a sharper focus on professional services and key operational areas, CFM was re-organised. Processes were realigned and job scopes were redefined. Much emphasis was placed on achieving cultural change, whilst managing the transition into a self-funding operational entity. Open communication channels, staff empowerment and participative decision-making were instituted.

A major review of key professional protocols was carried out with a re-documentation of major core activities. This resulted in updated guidelines for the release of bodies under the Medical Therapy, Education and Research Act; safe working in the mortuary and post-mortem areas; retention of human tissues and organs in coroner's cases; handling of the dead in event of contamination by biological and chemical agents; and mass fatality event operations.

Establishment of Key Performance Indicators

To better service its customers, CFM approached its key stakeholders to identify their requirements and established key turnaround time for services committed on service level agreements.

Performance data for FY 01: Turnaround Time (TAT)	
% of cases less than 30 days TAT for Coroner's cases *(Post-mortem report submitted to coroner within 30 days)*	90.19%
% SGH deaths registered less than 2 hours *(Death cases registration and claiming of bodies within 2 hours for cases from Singapore General Hospital)*	99.88%
% Coroner's cases registered less than 30 minutes *(Death cases registration and claiming of bodies within 30 minutes for Coroner's cases)*	100%
% Forensic Death Investigator cases responding in less than 2 hours *(Certifying of death cases for the public and institutions)*	100%

Professional Initiatives

Medical Mortality Review was initiated and carried out regularly to review all peri-operative deaths. A central homicide registry was created to monitor the progress of such cases. A Singapore Medical Council-accredited continuing medical education programme was also instituted.

Upgrading of the Mortuary Facilities

With the new emphasis on occupational safety and biohazards, the mortuary suite was upgraded. All existing mortuary tables were replaced with mobile docking stations, with a complete overhaul of drainage systems. Refrigeration storage facilities were replaced. An isolation suite with 3 docking stations replaced the old facility, with improved air exchange. A full-height glass viewing gallery that facilitates post-mortem demonstrations to medical students, police officers and professional visitors was created. A separate embalming room was also created with new facilities for storage of hazardous chemicals.

Focus was also placed on the quality of the public interface. It was noted that the waiting area for the public lacked sufficient lighting, an appropriate ambience and sufficient seating. Renovations were initiated to expand the waiting area, provide for a private interview room, and adequate administrative space for staff. Security concerns were also taken into account during the course of the renovations.

Zero-IN Process (ZIP) Panel

Under the auspices of PS21, CFM participated in a ZIP Panel Review chaired by the Ministry of the Environment in reviewing death certification processes so as to provide seamless service to the next-of-kin.

Training & Development

As part of the ongoing collaboration with the National University of Singapore, CFM's forensic pathologists have been appointed as part-time clinical teachers in the undergraduate medical teaching programme in forensic pathology. The forensic pathologists are also involved in the training of police and other law enforcement officers in medico-legal subjects. Further, 6 local and 3 foreign doctors including 2 who came under the Philippines-Singapore Action Plan, were attached to the Centre and trained in forensic pathology under the guidance and supervision of CFM's forensic pathologists.

2 research projects were completed and 7 papers were published in professional/academic journals. In addition, the professional staff delivered 18 presentations and lectures at local and overseas conferences and seminars.

The Year Ahead

In the year ahead, CFM will focus on building strategic relationships locally and internationally. One key priority will be to seek accreditation with the National Association of Medical Examiners (NAME) of USA, which is the only known standard that accredits Offices of Forensic/ Medical Examiners.


centre for
forensic
science

To excel in forensic science for the purpose of law enforcement, medico-legal investigations, and administration of justice.

Core Functions ▪ Its Criminalistics Laboratory examines physical and trace evidence for law enforcement agencies ▪ Its DNA Profiling Laboratory provides DNA profiling expertise for criminal investigation ▪ Its DNA Database Laboratory collaborates with the Police on a fully automated system for DNA samples ▪ Its Narcotics Laboratory conducts analysis of narcotic drugs in drug seizures and urine of drug abusers ▪ Its Toxicology Laboratory provides analytical services for drugs and other toxic substances for patients and post-mortem specimens including emergency toxicology analysis after office hours ▪ Its Document Examination Laboratory provides expert analysis and opinion in handwriting, signatures, typewriting, forgery, alteration on ink and paper and other related materials for both the public and the private sectors.

centre for forensic science

The **Centre for Forensic Science (CFS)**, one of HSA's centres, was formerly part of the Institute of Science and Forensic Medicine.

CFS provides a one-stop forensic science service and consultancy to law enforcement agencies, government ministries, hospitals, private organisations and individuals for criminal and medico-legal investigations and civil disputes. Its 7 laboratories provide specialised scientific, investigative and analytical expertise in the areas of criminalistics, DNA profiling, narcotics, toxicology and document examination.

For FY 01, CFS completed a total of 73,252 samples with a total revenue of $14.86 million.

Re-accreditation by ASCLD/LAB

CFS has achieved international standards and recognition by being one of the few non-US laboratories accredited by the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB), an international benchmark accreditation scheme.

In June 01, CFS was re-accredited by ASCLD/LAB for another 5 years in the disciplines of controlled substances, toxicology, trace evidence, serology, DNA, firearms/toolmarks and questioned documents. This re-accreditation demonstrates CFS' commitment to ensuring best practices to support the administration of justice in Singapore.

Workload Statistics

	Criminalistics Lab	DNA Profiling	Document Examination Lab	Narcotics I Lab	Narcotics II Lab	Toxicology Lab	Total
Sample Received	912	2,546	350	5,183	46,726	17,535	73,252
Work Value (Man Hours)	6,168	13,298	3,902	28,057	23,754	26,812	101,991

ASCLD/LAB Certified Inspectors

In August 01, 14 forensic scientists passed the ASCLD/LAB Inspector Training Course to be certified inspectors. One officer has since been appointed as inspector to audit the Florida Palm Beach County Sheriff's Office in December 01.

International Reference Laboratory for Seized Materials

In June 01, the Narcotics I Laboratory was invited by the United Nations International Drug Control Programme to be a reference laboratory for the seized materials group. This international collaboration re-affirms CFS' high quality service standards.

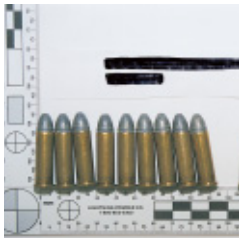
CNB-CFS Data Transmission

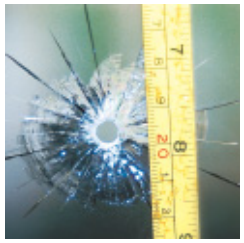
The electronic data transmission between the Central Narcotics Bureau (CNB) and Narcotics II Laboratory was fully established in 2001. The linkage facilitates the daily registration of urine

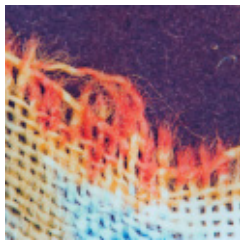
sample submissions and provides the means to upload analytical results onto CNB's main server. The system allows CNB to track online the receipt of urine samples and to receive the analytical results electronically.

New DNA Database Laboratory

In collaboration with the Police, CFS set up a DNA Database Laboratory in April 01 to build a fully automated system for DNA samples of convicted offenders. 9 officers were recruited and trained in-house with the necessary skill and knowledge for the new laboratory which targeted to be operational in 2002.







DNA Profiling Laboratory

In June 01, the DNA Profiling Laboratory introduced a new DNA paternity testing service using the PCR-STR technology for the private sector/clients. Since then, 112 cases comprising a total of 324 samples was submitted to the Laboratory.

Criminalistics Laboratory

The Criminalistics Laboratory acquired 5 additional infrared spectral libraries to augment its capabilities in Fourier-Transform infrared microspectrophotometry for the identification and comparison of unknown materials in trace amounts. This facilitated the identification of chemicals used in 18 anthrax hoax local cases after the 911 tragedy.

It also explored the potential of research with the Fire Investigation Branch (FIB) of the Singapore Civil Defence Force to enhance the fire investigation capability of FIB.

Document Examination Laboratory

The Document Examination Laboratory completed a research project on the "Investigation of Class Characteristics in the English Handwriting of the 3 Main Racial Groups - Chinese, Malay and Indian" in February 02. It has also conducted a series of workshop/seminar on "Screening of Forgeries and Counterfeits" for local banks and insurance companies since October 02.

Toxicology Laboratory

The Toxicology Laboratory has expanded its workplace drug testing programme with the validation of the kinetic interaction microparticles in solution (KIMS) method for the screening of barbiturates, methadone, methaqualone, phencyclidine, propoxyphene and benzodiazepines.

Scholarships

For the first time, 2 laboratory officers from CFS were awarded the Health Manpower Development Programme (HMDP) scholarships in September 01 to pursue their Masters in Science at universities in the United Kingdom.

Reseach & Development

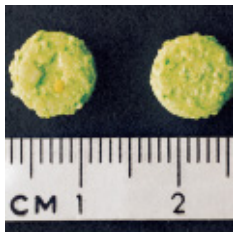
CFS has initiated 9 research projects and submitted 7 papers for presentation at international conferences.

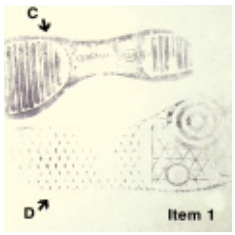
The Year Ahead

To better anticipate and meet clients' needs and requirements, CFS will forge closer rapport with major clients through discussions and signing of service level agreements.

The Criminalistics Laboratory has acquired a gas chromatograph (GC) equipped with an automated solid-phase microextraction (SPME) autosampler and a ceramic-tip flame ionisation detector to develop advanced techniques in sample preparation such as selective concentration and sample clean-up of trace amounts of organic compounds in a variety of matrices. This GC will be upgraded to tandem mass spectrometry to conclusively identify individual organic compounds, and to fully exploit the automated SPME autosampling capabilities.

The DNA Profiling Laboratory will validate the Y chromosome method to complement the existing STR DNA paternity testing and will also





validate the mitochondrial sequencing method for human remains.

The Narcotics II Laboratory will initiate a project to study the screening of ketamine in urine by Enzyme-Link Immunosorbent Assay (ELISA). Upon completion, the Laboratory will be able to provide a large scale screening programme for CNB to curb the abuse of ketamine in Singapore.

The Toxicology Laboratory will introduce the gas chromatography/mass selective detector method for the analysis of gamma hydroxy butyrate (GHB) in blood and urine specimens for suspected drug assisted sexual assault cases.


centre for
analytical
science

To excel in applying analytical science to safeguard public health by providing high quality, cost-effective and timely service to our clients.

Core Functions ▪ Its Food Laboratory, a WHO Collaborating Centre for Food Contamination Monitoring, provides analytical services ranging from testing for additives, contaminants and food composition to the Agri-food & Veterinary Authority and the industry ▪ Its Pharmaceutical Laboratory, a WHO Collaborating Centre for Drug Quality Assurance, provides analytical services for western medicines and Chinese proprietary medicines ▪ Its Cosmetics Laboratory provides analytical testing to support the regulation of cosmetics by CPA ▪ Its Industrial Health Laboratory provides analytical and consulting services on hazardous chemicals, biological monitoring, industrial products, inhalant abuse and assistance in the investigations of industrial accidents to the Ministry of Manpower ▪ Its Cigarette Testing Laboratory ensures that the tar and nicotine content of cigarettes are within statutory limits ▪ Its Environmental Laboratory supports pollution control by examining potable and treated water, trade effluents, reverse osmosis water, swimming lagoon water, aquarium water and detergents, for both public and private sectors ▪ Its Customs Laboratory certifies the alcoholic content of beverages and liquors for the purpose of classification and levying duty.

centre for analytical science

The **Centre for Analytical Science (CAS)**, one of HSA's 8 centres, incorporated the Health Sciences Division under the former Institute of Science and Forensic Medicine of the Ministry of Health.

CAS is the largest single-site testing laboratory facility in Singapore. It combines both highly qualified and experienced scientific expertise with state-of-the-art instrumentation. Its 7 laboratories provide analytical and consulting services to many government regulatory agencies and the private industries in the areas of food and drug safety, cosmetics, environmental and industrial health protection, and the testing of cigarettes and tariff items.

CAS handled a total of 19,732 samples and conducted 61,893 tests for the year in review.

Accreditation of Laboratories under ISO/IEC 17025

The laboratories in CAS were first accredited by Singapore Accreditation Council – Singapore Laboratory Accreditation Scheme (SAC-SINGLAS) under ISO/IEC Guide 25 in 1997. In FY 01, the laboratories sought accreditation under the new ISO/IEC 17025 in chemical, biological and environmental testing fields and the results would be announced in FY 02. Each laboratory went through a 2-week surveillance assessment by SAC-SINGLAS to demonstrate capability and competency to meet the highest international standards of laboratory management and practice.

Asia Pacific Laboratory Accreditation Co-operation

CAS and SAC-SINGLAS jointly organised a proficiency testing programme on food for the Asia Pacific Laboratory Accreditation Co-operation (APLAC) as part of Singapore's contribution to the region. CAS provided technical expertise in the programme which included sample homogeneity, validation of target value and statistical analysis of results from 90 participating laboratories from 30 countries in the Asia Pacific region.

International Collaboration

CAS works closely with the World Health Organisation (WHO) in various activities with the designation of its two laboratories as WHO Collaborating Centres.

Its Food Laboratory, a WHO Collaborating Centre for Food Contamination Monitoring, submitted 9,811 results of food contaminants from our national food surveillance programme to WHO in FY 01. The data provided useful information for WHO to make global comparison with other countries and helped WHO to identify trends and minimise risks of contaminants to consumers.

Its Pharmaceutical Laboratory, a WHO Collaborating Centre for Drug Quality Assurance, was re-accreditated for another 4 years from 2001 to 2005. Review of monographs for the International Pharmacopoeia and evaluation of test procedures and technical articles and validation of international standards were also carried out for WHO.

The 2 WHO Collaborating Centres have provided advanced training for about 20 WHO fellows from developing countries such as Nepal, Myanmar, Indonesia, India, Vietnam, Bangladesh and Sri Lanka. A training workshop on food safety for laboratory technicians in Myanmar was also conducted.

WHO Proficiency Testing Programme

CAS was invited by WHO to take part in a Proficiency Testing Programme, a new initiative which was open to selected government laboratories. It is a good opportunity for CAS to benchmark its Pharmaceutical Laboratory with other countries' laboratories as the Programme assesses the technical competence of government laboratories through a confidential system of testing of blind samples.

Quality Journey in Pursuit of Business Excellence

CAS embarked on the journey to business excellence with a Quality Excellence Workgroup formed in November 01. The workgroup was formed to conduct self-assessment using the Business Assessment for Continuous Improvement (BEACON) instrument to identify strengths and areas for improvement. A formal application would be made in early FY 02 for CAS to join the Singapore Quality Class (SQC).

Patent Filed

A novel system to extract bioactive ingredients from herbal medicinal products using pressurised liquid extraction was developed in its Pharmaceutical Laboratory. The new technique is more efficient and cost-effective than conventional methods. It takes only 20 to 30 minutes as compared to conventional methods which can take up to 18 hours. A patent is filed for this invention and there is prospect for the system to be commercialised.

International Publications

Through an emphasis of research and development, 5 papers were completed and accepted for publication in international journals in FY 01.

The Year Ahead

In the year ahead, CAS targets to achieve accreditation under the new ISO/IEC 17025 and the SQC award. Other than participating in WHO Global Proficiency Testing Programme for benchmarking of government laboratories, CAS is developing a work plan for the designation as a new WHO Collaborating Centre for Industrial Health. CAS is also developing new services in clinical trial support, safety of plastics, health supplements and carbon monoxide in cigarettes. In addition, it is working towards another patent for another novel extraction technique for herbal preparation.





senior management

top row from left to right

Dr Clarence Tan
Chief Executive Officer

Dr John Lim
Director, Centre for Pharmaceutical Administration
Ag Director, Centre for Drug Evaluation

A/Prof Patrick Tan
Director, Centre for Transfusion Medicine

Dr Paul Chui
Director, Centre for Forensic Medicine
Director, Office for Innovation & Enterprise

Dr Chow Shui Tse
Director, Centre for Forensic Science

bottom row from left to right

Mr Wong Yew Sin
Director, Centre for Medical Device Regulation

Mr Vincent Fong
Director, Corporate Management Group

Mr Stephen Chong
Director, Centre for Radiation Protection

Mrs Tan Shook Fong
Special Pharmaceutical Advisor

Mr Chua Teck Hock
Director, Centre for Analytical Science

A/Prof Ng Tju Lik
Senior Scientific Advisor
Quality Service Manager

principal officers

(as at august 02)

Chief Executive Officer
Dr Clarence Tan

Senior Scientific Advisor
Quality Service Manager
A/Prof Ng Tju Lik

Special Pharmaceutical Advisor
Mrs Tan Shook Fong

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Dr Paul Chui

Assistant Director, Organisation & Business Development
Ms Lim Peck Seah

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Vincent Fong

Deputy Director, Corporate Communications
Ms Jeannie Thng

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Philip Ngiam

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Deputy Director, Information Management
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Senior Deputy Director
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Yee Shen Kuan

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Head, Good Manufacturing Practice
Sia Chong Hock

Head, Good Distribution Practice
Sia Chong Hock

Head, Certification
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Head, Pharmacovigilance
Ms Chan Cheng Leng

Head, Information & Research
Ms Chan Cheng Leng

Head, Pharmacoeconomics & Drugs Utilisation
Mdm Suwarin Chaturapit

Head, Communications & International Liasion
Mdm Suwarin Chaturapit

Head, Regulatory Support
Ho Yu Nam

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Prof Vernon Oh

Assistant Director & Senior Medical Reviewer
Dr Gerard Wong

Senior Regulatory Scientist & Training Coordinator
Dr Vivian Chan

Regulatory Scientist & Corporate Management Coordinator
Tan Tek Seng

CENTRE FOR MEDICAL DEVICE REGULATION

Director
Wong Yew Sin

CENTRE FOR RADIATION PROTECTION

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Head, Environmental Radiation & Radioactive Waste Management
Stephen Chong

Head, Ionising Radiation Control
Ms Annie Tan

Head, Ionising Radiation Dosimetry
Ms Annie Tan

Head, Non-Ionising Radiation Control
Dr Phua Tan Tee

Head, Non-Ionising Radiation Dosimetry
Dr Phua Tan Tee

Head, Nuclear Safety & Emergency Planning
Tay Yong Heng

Head, Services & Consultancy
Tay Yong Heng

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Dr Diana Teo

Head, Blood Resources
Dr Tan Hwee Huang

Head, Clinical Service
Dr Lai Hock Choong

Nursing Administrator
Mrs Chua Chye Leng

Laboratory Manager
Ng Kok Quan

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Dr Teo Eng Swee

Principal Consultant Forensic Pathologist
Dr Wee Keng Poh

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Dr Michael Tay

Head, DNA Database Laboratory
Mrs Tan Wai Fun

Head, DNA Profiling Laboratory
Mrs Tan Wai Fun

Head, Document Examination Laboratory
Ms Lee Gek Kwee

Head, Narcotics I Laboratory
Dr Lee Tong Kooi

Head, Narcotics II Laboratory
Dr Lee Tong Kooi

Head, Toxicology Laboratory
Dr Danny Lo

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Head, Industrial Health Laboratory
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Head, Cosmetics Laboratory
Mrs Wong Geok Eng

Head, Cigarette Testing Laboratory
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Head, Environmental Laboratory
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